

REMARKS

Claims have been amended to eliminate multiple dependencies, to maintain proper antecedent basis, and otherwise to conform to U.S. practice. In so doing, claims 15, 16 and 17 now contain recitations of claims 1, 2 and 13. Thus, no new matter has been added. Accordingly, Applicants respectfully request entry of the amendments.

The Office has required restriction of claims 1-17 under 35 U.S.C. §§ 121 and 372, on the ground that the claims are not so linked as to form a single general inventive concept under PCT Rule 13.1. Accordingly, Applicants have been required to elect a single invention as between the following, namely:

Group I, claims 1-14, drawn to a method for the sterilization of a glucocorticosteroid; and

Group II, claims 15-17 drawn to a composition obtained by the invention of Group I.

The Office has alleged that the special technical feature of Group I, which is the method for the sterilization of a glucocorticosteroid, does not represent a contribution over the prior art in view of the teachings of U.S. Patent 6,066,292, to Purwar ("Purwar"), which allegedly teaches "a method for sterilizing a pharmaceutical formulation comprising a suspension of a water-insoluble pharmaceutical, comprising the steps of heat-sterilizing. . ." (abstract) and specifically wherein the pharmaceutical is a hydrocortisone (abstract), which encompasses a glucocorticosteroid."

In response to the request for restriction, Applicants elect Group I, claims 1-14. This election is made with/without traverse. Applicants reserve comment on the merits of Purwar until substantive examination.

The Office has also requested, in the event of an election

of Group I, an additional election of a species as between budesonide and beclomethansone dipropionate. In response, Applicants hereby elect the species budesonide. Elected claims 1-10 and 12-14 read on the elected species.

This election is made with traverse. The Office Communication alleges that there is an examination and search "burden" for these allegedly patentably distinct species due to their mutually exclusive characteristics, such that they'd require a different field of search, the prior art applicable to one species would not likely be applicable to the other species, and/or the species are likely to raise different non-prior art issues under § 101 and/or § 112, first paragraph. Yet, the Communication sets forth no specific classifications, specific prior art publications or non-prior art issues. Accordingly Applicants respectfully submit that in the absence of any substantiation of these allegations, that claim 11, which is directed to beclomethansone dipropionate, be examined on the merits as well.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: April 29, 2009

Respectfully submitted,

By 

Stephen J. Brown

Registration No.: 43,519
LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP
600 South Avenue West
Westfield, New Jersey 07090
(908) 654-5000
Attorney for Applicant